REMARKS

Pursuant to the response filed on May 16, 2010 and according to discussions with Examiner Frazier during the interview on April 15, 2010, the attached declaration contains sworn statements detailing efforts to produce the composition of Kasahara, efforts to adapt the Kasahara aqueous solution for use in the presently claimed method, i.e., making it into a gel rather than an aqueous solution, and a side-by-side comparison of the physical properties of this gel based on Kasahara's ingredients with the Dianatal® gel for use in the claimed method.

In his declaration, Dr. Schaub provides evidence that the Kasahara aqueous solution was prepared (see Figure 1), but that an aqueous solution is not useful in human birthing methods, and specifically in the presently claimed method because an aqueous solution is not effective in keeping the birth canal surface covered with said lubricant composition so that a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered. An aqueous solution would not form a lubricant layer, but instead be expelled by the mother's movement or by the item to be delivered during birth. The present claims exclude the use of an aqueous solution by requiring that the composition be in the form of a paste, gel, cream, suppository, or foam.

Dr. Schaub then details how he sought to use the teachings of Kasahara to produce a gel for use in the claimed method, and obtained the gel shown in Figure 2. Dr. Schaub provides his expert opinion that, in addition to the factors that make Kasahara's composition unsuitable for use detailed in the May 16th response, i.e., lack of proper lubricity, appearance, reproducibility, standard guideline for production,

sterility, commercial applicability, or shelf-life, a gel made according to Kasahara is too viscous to properly cover or coat the birth canal as is required by the presently claimed method because it congeals and does not easily spread, lacks gliding properties as it is too thick, and has a dark brown color that makes it commercially unacceptable for human use.

Further, Dr. Schaub provides a picture of a side-by-side comparison of Dianatal® with the gel adapted from Kasahara (see Figure 3). Dr. Schaub attests that while Dianatal® is a clear gel that has suitable gliding, bioadhesive, and coating properties for use in the claimed method, the gel adapted from Kasahara is a dark brown, visibly very viscous substance, is therefore difficult to apply and is non-coating. Thus, Dr. Schaub demonstrates that the composition of Kasahara cannot be used in the presently claimed method and cannot be adapted in a way to be suitable for such use.

Applicants respectfully request that the Examiner consider the enclosed experimental comparisons and efforts as a showing of the Applicant's non-obvious contribution to the art, which is defined by the present claims.

The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

By __/Robert B. Murray/ _____
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Enclosure: Declaration of Dr. Schaub

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